



To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the claimant's attorney must complete Part III if the claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.<sup>4</sup> See Settlement Agreement §§ IV.B.1.a. & I.22.

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describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for sixty-one days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for sixty days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

In June 2014, Ms. Schatz submitted a completed Green Form to the Trust signed by her attesting physician, Azam U. Anasari, M.D., F.A.C.C., F.A.H.A. ("Dr. Ansari"). Based on an echocardiogram dated September 14, 2013,<sup>5</sup> Dr. Ansari attested in Part II of Ms. Schatz's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.<sup>6</sup> Based on such findings, Ms. Schatz would be entitled to Matrix A-1, Level II benefits in the amount of \$678,025.<sup>7</sup>

In the report of the March 24, 2003 echocardiogram, Dr. Ansari stated that Ms. Schatz had moderate mitral regurgitation, which he measured at 29%. Under the definition set forth in the Settlement Agreement, moderate mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

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5. Because the September 14, 2013 echocardiogram of Ms. Schatz was performed after the end of the Screening Period, she relied on an echocardiogram dated March 24, 2003 to establish her eligibility to receive Matrix Benefits.

6. Dr. Ansari also attested that Ms. Schatz suffered from New York Heart Association Functional Class III symptoms. This condition is not at issue in this claim.

7. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and with one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is among the complicating factors needed to qualify for a Level II claim.

The Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant who is diagnosed with mild mitral regurgitation<sup>8</sup> by an echocardiogram that was performed between the commencement of Diet Drug use and the end of the Screening Period. See id. § IV.B.2.d.(2)(a). As the Trust does not contest the entitlement of Ms. Schatz to Level II benefits, the only issue before us is whether she is entitled to payment on Matrix A-1 or Matrix B-1.

In August 2014, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., F.A.S.E. ("Dr. Irani"), one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for finding that the March 24, 2003 eligibility echocardiogram demonstrated moderate, as opposed to mild, mitral regurgitation. Specifically, Dr. Irani explained, mitral regurgitation "appears mild on review of all motion images. Still frame image in one view traced giving appearance of larger jet but no hint of moderate [mitral regurgitation] on remainder of" the echocardiogram.

Based on Dr. Irani's finding that Ms. Schatz had only mild mitral regurgitation between the commencement of Diet Drug

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8. Under the Settlement Agreement, mild mitral regurgitation is defined as occurring when "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitation jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

use and the end of the Screening Period, the Trust issued a post-audit determination that Ms. Schatz was entitled only to Matrix B benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims (the "Audit Rules"), Ms. Schatz contested this adverse determination.<sup>9</sup> In contest, Ms. Schatz argued that the auditing cardiologist should have measured still frame images from her March 24, 2003 echocardiogram rather than "eyeballing" the level of her mitral regurgitation. She also contended that she was entitled to Matrix Benefits because the Trust informed her in connection with the Screening Program that her March 24, 2003 echocardiogram demonstrated moderate mitral regurgitation.<sup>10</sup>

In addition, Ms. Schatz submitted a verified statement from Dr. Ansari, who confirmed his finding of moderate mitral

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9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Schatz's claim.

10. In addition, Ms. Schatz identified a number of individuals whom she asserted did not act within the time periods allowed by the Audit Rules in connection with the audit of her claims. There is no support for her contentions. Further, even if they are true, these assertions do not constitute prejudice that would require the payment of an otherwise uncompensable claim. As we previously discussed in PTO No. 6339, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument without, at a minimum, some showing of prejudice." Mem. in Supp. of PTO No. 6339, at 13 n.10 (May 25, 2006).



regurgitation based on Ms. Schatz's March 24, 2003 echocardiogram.

Dr. Ansari explained that, unlike the auditing cardiologist, he measured Ms. Schatz's level of mitral regurgitation. He also stated that given Ms. Schatz's pre-Diet Drug health her mitral regurgitation was likely caused by her Diet Drug use. In support of Dr. Ansari's conclusion, Ms. Schatz included still frame images that purportedly demonstrated moderate mitral regurgitation.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist.

Dr. Irani submitted a declaration in which he again concluded that Ms. Schatz's March 24, 2003 echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Irani stated:

11. In contest, I re-reviewed Claimant's March 24, 2003 Eligibility Echocardiogram. I traced and digitized the left atrial area ("LAA") and regurgitant jet area ("RJA") in several frames. The LAA traced by Dr. Ansari is not the largest LAA found in the study. When I measured a representative LAA and compared it to that identified by Dr. Ansari, I found that Dr. Ansari's measurement was 28% smaller than my own.
12. As a general rule, the same regurgitant jet shown in a still frame image should be seen when advancing a study frame by frame. The mitral regurgitation seen on the still frame image identified by Dr. Ansari is not evident in the frames immediately before or afterwards.
13. I averaged my three most generous measurements of [mitral regurgitation],

and arrived at an RJA/LAA ratio of 16%. When measuring the very best jet (most accurate) of [mitral regurgitation], I arrived at an RJA/LAA ratio of only 12%. Even retracing the jets closest in size to those seen on the still frame submitted by Ms. Schatz's attesting physician, mitral regurgitation is only mild.

The Trust then issued a final post-audit determination, again determining that Ms. Schatz was entitled only to Matrix B-1, Level II benefits. Ms. Schatz disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Ms. Schatz's claim should be paid. On April 20, 2015, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 9407 (Apr. 20, 2015).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Ms. Schatz then served a response upon the Special Master. The Trust submitted a reply on June 19, 2015, and Ms. Schatz submitted a sur-reply on July 20, 2015. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>11</sup> to review claims after the Trust and the claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C.

("Dr. Vigilante"), to review the documents submitted by the Trust and Ms. Schatz and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that she suffered from at least moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See Audit Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this finding, we must enter an Order directing the Trust to pay the

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge - helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. See id.



claim in accordance with the Settlement Agreement. See Audit Rule 38(b).

In support of her claim, Ms. Schatz repeats the arguments raised in contest. In addition, Ms. Schatz contends that she has established a reasonable medical basis for her claim because: (1) the Trust misquoted Dr. Irani's supplemental declaration when it said Dr. Ansari's measurement was "28% greater than my own," because it should be "28% smaller than my own" and misquoted her argument regarding "eyeballing" to be "world of the court" rather than "world of cardiology"; (2) she included three consecutive still frame images that allegedly demonstrate moderate mitral regurgitation (which she contends satisfies the Trust's contention that "a true jet of mitral regurgitation must last at least one-tenth of a second"); (3) Dr. Irani's opinion cannot be relied upon, as it is internally inconsistent; (4) Dr. Irani did not "show his work"; and (5) the Trust did not follow the requirements of the Settlement Agreement.

Ms. Schatz also submitted another verified statement from Dr. Ansari, who again confirmed his finding of moderate mitral regurgitation on the March 24, 2003 echocardiogram. Specifically, Dr. Ansari stated that the mitral regurgitation on the echocardiogram was determined from the maximum jet area, as required by the Settlement Agreement. He also observed that the

mitral regurgitation in the still frame images consisted of two regurgitant jets, but that the auditing cardiologist only measured one of these jets. Dr. Ansari further explained that the auditing cardiologist's review and opinion do not meet the requirements of the Settlement Agreement. In addition, he contended that the discrepancies between his findings and those of the auditing cardiologist were due to "significant intra-reader variability." Finally, Dr. Ansari maintained that Ms. Schatz's echocardiogram "is best interpreted within the clinical context at the time" that the echocardiogram was performed.

In response, the Trust asserts that the findings of the auditing cardiologist demonstrate there is no reasonable medical basis for Dr. Ansari's finding of moderate mitral regurgitation on the March 24, 2003 echocardiogram. In particular, the Trust notes that the still frame images on which Dr. Ansari relied were not representative of the level of mitral regurgitation throughout the study. The Trust also argues that the court has repeatedly and consistently approved the use of "eyeballing" in determining the level of regurgitation on an echocardiogram. Finally, the Trust contends that the letter reporting the initial results of Ms. Schatz's March 24, 2003 echocardiogram as part of the Screening Program do not require the payment of Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed the echocardiogram of Ms. Schatz and concluded that there was no reasonable medical basis for finding that Ms. Schatz's March 24, 2003 echocardiogram demonstrated at least moderate mitral regurgitation. Specifically, Dr. Vigilante determined, in pertinent part:

After reviewing the Special Master Record, I re-reviewed the tape of the Claimant's March 24, 2003 echocardiogram study. I paid particular attention to the cardiac cycles during which the still frames were taken by Dr. Ansari. Visually, there was only very mild mitral regurgitation present. Once again, I digitized the cardiac cycles in both the apical two and apical four chamber views in which the representative mitral regurgitant jet appeared most impressive. I then measured the RJA and LAA by electronic calipers. The mitral regurgitation was most impressive in the apical two chamber view. Remeasurement of the largest representative RJA in the apical two chamber view was 1.4 cm<sup>2</sup>. The LAA in the apical two chamber view was 17.0 cm<sup>2</sup>. Therefore, the largest representative RJA/LAA ratio was 8%. This ratio did not come close to approaching a ratio of 20%. The mitral regurgitation was only trace in the apical four chamber view as the jet was within 1 cm of the mitral annulus. I paid particular attention to the time frames emphasized by Dr. Ansari. The cardiac cycles during the time frames clearly demonstrate mild and not moderate mitral regurgitation. The supposed RJA's [sic] traced in these still frame photos are not accurate measurements of the RJA. Instead, these measurements contain low velocity and non-regurgitant flow. The true degree of mitral regurgitation is mild.

. . . . .

[T]here is no reasonable medical basis for a finding of moderate or greater mitral regurgitation based on Claimant's echocardiogram of March 24, 2003. That is, when appropriate quantitative measurements are performed on this study, only mild mitral regurgitation is present. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

In response to the Technical Advisor report, Ms. Schatz relies primarily on her previous arguments to establish that her March 24, 2003 echocardiogram demonstrates moderate mitral regurgitation. She also takes exception to the Technical Advisor Report because it does not mention the word "mosaic" in characterizing her regurgitant jet. In addition, Ms. Schatz contends that the court should disregard the Technical Advisor Report because Dr. Vigilante refers to the parasternal long-axis view when she believes he should be referring to the apical view and because the report "is merely a manipulative narrative" of the record. Finally, she argues that there is a reasonable medical basis for her claim because her original diagnosis of moderate mitral regurgitation was the result of a "thorough, measured, and unhurried cardiac examination" by a Qualified Physician.

After reviewing the entire Show Cause record, we find the arguments of Ms. Schatz to be without merit. As an initial matter, we disagree with Ms. Schatz that Dr. Ansari's submissions

and still-frame images provide a reasonable medical basis for finding that the March 24, 2003 echocardiogram demonstrates moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than Ms. Schatz contends. For example, as we have previously explained, conduct "beyond the bounds of medical reason" can include, among other things, failing to review multiple loops and still frames, failing to examine the regurgitant jet throughout a portion of systole, and characterizing low velocity flow as mitral regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14. 2002).

We also have held that for a reasonable medical basis to exist a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout the echocardiogram. See, e.g., Mem. in Supp. of PTO No. 6997 at 11 (Feb. 26, 2007); see also, e.g., In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). To conclude otherwise would allow claimants who do not have the requisite level of regurgitation to receive Matrix Benefits. This would be contrary to the intent of the Settlement Agreement. See Mem. in Supp. of PTO No. 6997, at 11.



Here, Dr. Irani reviewed the March 24, 2003 echocardiogram and determined that it demonstrated mild mitral regurgitation. Dr. Irani also reviewed the still-frame images that Dr. Ansari provided and determined that they were not representative of the level of mitral regurgitation shown throughout the echocardiogram. Dr. Irani also re-reviewed the echocardiogram of Ms. Schatz following her contest and concluded that the LAA traced by Dr. Ansari was not the largest LAA on the study. He also observed that the regurgitant jet shown in the still-frame images was not seen on the tape in the period before or after the still frame.<sup>12</sup>

In addition, using electronic calipers to measure the most "impressive" mitral regurgitation, Dr. Vigilante determined that only mild mitral regurgitation was present on the March 24, 2003 echocardiogram of Ms. Schatz. Dr. Vigilante also reviewed the still-frame images provided by Dr. Ansari and determined that "[t]he supposed RJA's [sic] traced in these still frame photos are not accurate measurements of the RJA. Instead, these measurements contain low velocity flow and non-regurgitant

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12. We also reject Ms. Schatz's contention that Dr. Irani contradicted himself when he found that the average of the three most generous mitral regurgitation measurements was 16%, while his "very best jet" measured only 12%. As Dr. Irani explained, he used the term "very best jet" to mean "most accurate," not largest, as Ms. Schatz suggests.

flow."<sup>13</sup> Such unacceptable practices cannot provide a reasonable medical basis for the representation that the echocardiogram of Ms. Schatz demonstrated moderate mitral regurgitation.<sup>14</sup>

We also disagree with the argument of Ms. Schatz that the auditing cardiologist's use of visual estimation was improper. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not require that actual measurements must be made on the echocardiogram. As we have explained, "[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology.'" See Mem. in Supp. of PTO No. 2640 at 15. Ms. Schatz essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine whether a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and the argument made by Ms. Schatz is contrary

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13. As Dr. Vigilante found low rather than high velocity flow, it is not surprising that he did not refer to mosaic regurgitation. We have previously found that "[o]n a color flow Doppler echocardiogram, mitral regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole." Mem. in Supp. of PTO No. 2640 at 10-11 (footnote omitted).

14. For all of these reasons, we reject the arguments made by Ms. Schatz that Dr. Vigilante did not "show and tell" and that his conclusions were "a manipulative narrative" of the record.

to the "eyeballing" standards that we previously evaluated and accepted in PTO No. 2640.<sup>15</sup>

Further, the reliance of Ms. Schatz on her Screening Program echocardiogram to support her assertion that there is a reasonable medical basis for her claim is misplaced. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Settlement Agreement § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to

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15. In any event, Dr. Irani and Dr. Vigilante each provided specific measurements.

seek Matrix Benefits. See id. § IV.B.1. Further, adopting the position endorsed by Ms. Schatz would be inconsistent with Section VI.E of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as with this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits.<sup>16</sup> See Mem. in Supp. of PTO No. 2662, at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline the request of Ms. Schatz to interpret the Settlement Agreement in this fashion.<sup>17</sup>

Finally, to the extent that Ms. Schatz asserts that she is entitled to Matrix Benefits because her condition is a result of her ingestion of Diet Drugs, such an assertion is erroneous. Causation is not at issue in resolving claims for Matrix

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16. For this reason, we reject the arguments of Ms. Schatz that the Trust failed to follow the requirements of the Settlement Agreement and that the relevant echocardiogram is best interpreted at the time it was originally conducted.

17. In fact, the letter from the Trust regarding the results of Ms. Schatz's Screening Program echocardiogram specifically stated, "[I]f you at any time file a GREEN Form seeking Fund B Matrix-Level Benefits, the Trust will determine Diet Drug use, duration of use, whether the Diet Drug Recipient was diagnosed as FDA Positive, and any other aspect of claim eligibility independently and without regard to any of the Trust determinations which qualified you to receive any Fund A Benefits to date."

Benefits. Rather, claimants are required to show that they meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred . . . .

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that "individual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation." Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if the claimant is diagnosed with mild mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a). We must apply the Settlement Agreement as written. Accordingly, the assertion of Ms. Schatz that her medical condition was caused by her ingestion of Diet



Drugs is irrelevant to the issue before the court.

For the foregoing reasons, we conclude that Ms. Schatz has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Schatz's claim for Matrix A-1 benefits and of the related derivative claim submitted by her spouse.